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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/564,785

01/17/2006

Philippe Msika

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EXAMINER

GULLEDGE, BRIAN M

ART UNIT

PAPER NUMBER

1612

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/564,785	<b>Applicant(s)</b> MSIKA ET AL.	
	<b>Examiner</b> Brian Gullede	<b>Art Unit</b> 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 10 August 2010.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 4,6-10 and 26-34 is/are pending in the application.
- 4a) Of the above claim(s) 26-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 4,6-10 and 30-34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>8/10/10</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Previous Rejections***

Applicants' arguments, filed 10 August 2010, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

### ***Information Disclosure Statement***

An information disclosure statement filed after a non-final rejection (as with the IDS filed 10 August 2010) requires either a statement as specified in 37 CFR 1.97(e) or a fee as set forth in 37 CFR 1.17(p). The information disclosure statement filed 10 August 2010 does not include the fee set forth in 37 CFR 1.17(p). And while the statement was provided that each of the two items were first cited in a communication from a foreign patent office not more than three months prior to the filing of the statement, this does not appear to be correct. WO 98/47479 and FR 2778565, cited on the IDS, were previously cited on an IDS filed 17 January 2006, and were cited with regards to PCT/FR2004/001907. As this citation was more than three months prior to the date of the statement provided, the statement is not considered proper.

Applicant also states that two references not considered on the IDS filed 17 January 2006 are of record in this application, as the Saleem et al. reference was initialed on the IDS filed 2 March 2006, and the Gogly et al. references was cited by the examiner in the restriction requirement. If these reference were either initialed on another IDS (as was the Saleem et al.

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reference on the IDS received on 29 March 2006 – no IDS was received on 2 March 2006) or listed as a reference cited by the previous Examiner, then the record presently indicates that these references have been considered, even if an earlier duplicate listing was not considered.

***Claim Rejections - 35 USC § 112, 2<sup>nd</sup> Paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

**Claims 4, 6-10, and 33-34 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.** The Applicant argues that the rejection is not proper, because the term “lupeol-rich extract” is clearly explained in the specification to be an extract with greater than 30 wt% lupeol, advantageously greater than 50 wt% and even more advantageously between 70 and 100 wt%.

The Examiner is not persuaded by this argument. The term “lupeol-rich extract” is discussed in the specification in several places (see for example page 6, lines 16-18; page 12, lines 19-22; & page 19, example 1). However, there are multiple descriptions provided for what can be considered a “lupeol-rich extract.” The Examiner does not consider any single one of these discussions to be limiting to the term in the claims. A single definition was not put forth, as no single one of the each of the at least four differing descriptions was stated to define and limit the claimed term. Thus, the claims are not considered to be limited by the alternative descriptions put forth, and the specification does not provide a standard for ascertaining the requisite degree. As such, one of ordinary skill in the art would not be reasonably apprised of the

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scope of the invention, because it cannot be clearly determined whether a lupeol extract meets the conditions necessary to be considered lupeol-rich.

***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

**Claims 4, 6, 9-10, and 30-34 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Msika et al. (US Patent 6,146,616) in view of Murad (US Patent 5,972,999).** Applicant argues that the rejection is not proper. Applicant states that the PTO contends that the lupine oil taught by Msika et al. must contain lupeol, an assertion that is incorrect. Applicant states that Msika et al. teaches that lupine oil has a high content of polyphenols, and that lupeol is not a phenol and Msika et al. does not teach or suggest lupine oil contains lupeol. Applicant then argues that the lupine oil taught by Msika et al. would not be understood to be a lupeol-rich extract as claimed, because table 1 disclosed by Msika et al. shows that the  $\alpha$ -lupeol content of lupine oil is from 0.1 to 1 wt%.

The Applicant further argues that, as shown in the table provided in the arguments, the amount of lupeol present in lupine oil differs from the amount of lupeol present in a “lupeol-rich extract.” The Applicant states that as the term “lupeol-rich extract” is defined in the specification to be an extract with greater than 30 wt% lupeol, and as such the lupine oil cannot meet the claimed limitation.

The Examiner acknowledges these arguments, but does not consider them persuasive. Initially the Examiner responds to the argument that the lupine oil disclosed by Msika et al. does

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not contain lupeol. The Applicant also stated and referred to a table disclosed by Msika et al. that teaches the amount of lupeol present, and that this amount does not meet the claimed "lupeol-rich extract" limitation. The Examiner notes that both these arguments cannot be correct. The Applicant argues that Msika et al. does not teach that lupine oil contains lupeol, and then the Applicant cites a table from Msika et al. where Msika et al. teaches the amount of lupeol present (an amount that is non-zero). As the Examiner notes that the lupine oil composition put forth by Msika et al. (table in column 4) is stated to contain 0.1 to 1 wt% lupeol, the first argument is considered moot.

With regards to the term "lupeol-rich extract," the Applicant argues that the term is defined in the specification to be greater than 30 wt% lupeol. However, the Examiner does not agree. The term is discussed in the specification in several places (see for example page 6, lines 16-18; page 12, lines 19-22; & page 19, example 1). However, there are multiple descriptions provided for what can be considered a "lupeol-rich extract." The Examiner does not consider any single one of these discussions, however, to be limiting to the term in the claims. A single definition was not put forth, as no one of the each of the at least four differing descriptions was stated to define and limit the claimed term. Thus, the claims are not considered to be limited to extracts with at least 30 wt% lupeol.

Additionally, even if *en arguendo* claim 4 were limited to one of these descriptions, the rejection would still be considered proper. The claims recite using a composition "comprising a lupeol-rich extract." The composition contains lupeol, and as the composition uses *comprising* language, the composition is open-ended and does not exclude any other ingredients. If, for the sake of argument, the "lupeol-rich extract" was taken to require 100% lupeol (the highest

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possible amount, the largest difference possible between the claims and the lupine oil taught by Msika et al.), then the rejection would still be considered proper. The amount of the "lupeol-rich extract" is only at most limited to from 0.001 to 10 wt% of the entire composition (instant claim 10). Thus, the highest amount of the active lupeol present would also be from 0.001 to 10 wt%. However, Msika et al. teaches lupeol is present in the oil in from 0.1 to 1 wt% (example 1), and that this oil is used in 5 wt% (column 6, example II, first embodiment). With 5 wt% lupine oil present in the composition, and the lupeol present in from 0.1 to 1 wt% of said oil, the lupeol is present in from 0.005 to 0.05 wt% of the composition. This range reads on and lies entirely within the range recited by instant claim 10. While there may be other ingredients present as a consequence of using lupine oil that would not be present when using pure lupeol, the claims do not exclude such ingredients.

**Claim 7 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Msika et al. (US Patent 6,146,616) and Murad (US Patent 5,972,999) as applied to claim 4 above, and further in view of Hernández-Pérez et al. (*Dermatol. Drug.*, 2002, 28(12), pages 1124-1130).** Applicant argues that the rejection is not proper, as Hernández-Pérez et al. does not cure the deficiencies of the combination of Msika et al. and Murad, as discussed above. The Examiner maintains the rejection, as Msika et al. and Murad are not considered deficient, as discussed above.

**Claim 8 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Msika et al. (US Patent 6,146,616) and Murad (US Patent 5,972,999) as applied to claim 4 above, and**

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**further in view of Herman (US Patent 5,190,979).** Applicant argues that the rejection is not proper, as Herman does not cure the deficiencies of the combination of Msika et al. and Murad, as discussed above. The Examiner maintains the rejection, as Msika et al. and Murad are not considered deficient, as discussed above.

### ***Conclusion***

No claims are allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Gullede whose telephone number is (571) 270-5756. The examiner can normally be reached on Monday-Thursday 6:00am - 3:00pm.



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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BMG

/Frederick Krass/  
Supervisory Patent Examiner, Art Unit 1612